

REMARKS

Claims 60-73, 76-78, 81-83, 86-88, 91-93, 96-98, 101-103, 106-108, 111-113, 116-118, 121-123, 126-128, 131-133, 136-138, 141-143, 145-148, 151-153, 156-158, 161-163, 166-168, 171-173, 176-178, 181-183, 186-188, 191-193, 196-198, 201-203, 206-208, 211-213, 216-218, 221-223, 226-228, 231-233, 236-238, 240-243, 246-248, 250-252, 255-257, 260-262, 265-268, 271-273, 276-278, 281-284, 287-289, 292-294, 297-299, 302-304, 307-309, 312-314, 317-319, 322-324, 327-329, 332-340, 341-349, 351-352, 354, 355, 357-358, 360-366, 368-369, 371-372 and 374-469 are pending in the present application.

Claims 341-349, 351-352, 354, 355, 357-358, 360-366, 368-369, 371-372 and 374-469 are allowed.

Claims 60-73, 76-78, 81-83, 86-88, 91-93, 96-98, 101-103, 106-108, 111-113, 116-118, 121-123, 126-128, 131-133, 136-138, 141-143, 145-148, 151-153, 156-158, 161-163, 166-168, 171-173, 176-178, 181-183, 186-188, 191-193, 196-198, 201-203, 206-208, 211-213, 216-218, 221-223, 226-228, 231-233, 236-238, 240-243, 246-248, 250-252, 255-257, 260-262, 265-268, 271-273, 276-278, 281-284, 287-289, 292-294, 297-299, 302-304, 307-309, 312-314, 317-319, 322-324, 327-329, and 332-340 stand rejected.

No new amendments or claims are included with this response. Reconsideration of the application and an Advisory Action is respectfully requested in view of the following remarks. For the Examiner's convenience, Applicant's remarks are presented in the order in which they were raised in the Office Action.

A. Examiner interview

Applicants appreciate the Examiner's explanation of her concern with alleged lack of support for the *genus* of "at least 12 contiguous nucleotides ... wherein said polynucleotide has a maximum length of XXX" as the basis of the rejection in a telephonic interview with Applicants' representative Shantanu Basu, on March 8th, 2006.

B. Allowable claims

Applicants appreciate the Examiner's determination that claims 341-349, 351-352, 354, 355, 357-358, 360-366, 368-369, 371-372 and 374-469 are allowed.

C. Claim Rejections Under 35 U.S.C. § 112, first paragraph

Claims 60-73, 76-78, 81-83, 86-88, 91-93, 96-98, 101-103, 106-108, 111-113, 116-118, 121-123, 126-128, 131-133, 136-138, 141-143, 145-148, 151-153, 156-158, 161-163, 166-168, 171-173, 176-178, 181-183, 186-188, 191-193, 196-198, 201-203, 206-208, 211-213, 216-218, 221-223, 226-228, 231-233, 236-238, 240-243, 246-248, 250-252, 255-257, 260-262, 265-268, 271-273, 276-278, 281-284, 287-289, 292-294, 297-299, 302-304, 307-309, 312-314, 317-319, 322-324, 327-329, and 332-340 stand rejected under 35 U.S.C. § 112, first paragraph, for alleged lack of written description.

Specifically the Examiner alleges that the Specification, as filed, lacks support for the claim limitation of at least 12 contiguous nucleotides but less than "some arbitrary length." (Office Action at 2-3). In a telephone interview with Applicants' representative, the Examiner noted her concern with alleged lack of support for the *genus* of "at least 12 contiguous nucleotides ... wherein said polynucleotide has a maximum length of XXX."

Applicants respectfully traverse. The minimum and maximum lengths recited in the claims are not arbitrary but are specific lengths of polynucleotide sequences disclosed in the Specification, which also provides written description support under 35 U.S.C. § 112, first paragraph for the claim term "[a] polynucleotide comprising a contiguous sequence that is identical to a sequence of at least 12 contiguous nucleotides shown in either strand of the nucleotide sequence in any of Figures 1, 3 or 4, wherein said polynucleotide has a maximum length of " 353, 586, 108 or 161 nucleotides as recited in claims 60-73, 78, 81-83, 86 and 87. The remainder of the rejected claims stand rejected on the basis of their dependence from claims 60-73, 78, 81-83, 86 and 87.

A description of a genus of DNAs may be achieved by means of a recitation of a representative number of DNA sequences

Although the Federal Circuit has used various expressions to set forth the standards for compliance with § 112, it is clear that the written description requirement does not require a patent applicant to provide a verbatim description of all his claims in the disclosure. *See Union Oil Co. Of Cal. v. Atl. Richfield Co ("UNOCAL"), 208 F.3d 989, 997-1001 (Fed. Cir. 2000)*. Rather, "if a person of ordinary skill in the art would have understood the inventor to have been in possession of the claimed invention at the time of filing, even if every nuance of the claims is

not explicitly described in the specification, then the adequate written description requirement is met." *In re Alton*, 76 F.3d 1168, 1175 (Fed. Cir. 1996); see also *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563 (Fed. Cir. 1991)("The test for sufficiency of support in a patent application is whether the disclosure of the application relied upon 'reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter.'")(citing *Ralston Purina Co. v. Far-Mar-Co, Inc.*, 772 F.2d 1570, 1575 (Fed. Cir. 1985)).

The written description requirement does not dictate that the applicant describe the invention exactly. Rather, what is required is that, as of the filing date, the inventor convey with reasonable clarity to those skilled in the art that the inventor was in possession of the subject matter claimed. See *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 U.S.P.Q.2d (BNA) 1111, 1117 (Fed. Cir. 1991). In order to comply with the written description requirement, the specification "need not describe the claimed subject matter in exactly the same terms as used in the claims; it must simply indicate to persons skilled in the art that as of the [filing] date the applicant had invented what is now claimed." *All Dental Prodx LLC v. Advantage Dental Products Inc.*, 309 F.3d 774, 779, 64 U.S.P.Q.2d 1945, 1948 (Fed. Cir. 2002) (citations omitted).

One shows that one is "in possession" of an invention by describing the invention with all its claimed limitations through "such descriptive means as words, structures, figures, diagrams, formulas, etc., that fully set forth the claimed invention." *Hyatt v. Dudas* 393 F. Supp. 2d 1 (D.C. Cir. 2005) citing *Lockwood v. Am. Airlines, Inc.*, 107 F.3d 1565, 1572 (Fed. Cir. 1997).

The Federal Circuit has addressed the manner by which a genus of cDNAs might be described. "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus." *University of California v. Eli Lilly and Co.*, 119 F.3d 1559, 1568, 43 U.S.P.Q.2d 1398, 1406 (Fed. Cir. 1997)

(i) Claim term: at least 12 contiguous nucleotides ... wherein said polynucleotide has a maximum length of 353 nucleotides

Claims 60, 62, 64, 66, 68, 70 and 71 specify "[a] polynucleotide comprising a contiguous sequence that is identical to a sequence of at least 12 contiguous nucleotides shown in either

strand of the nucleotide sequence in ... wherein said polynucleotide has a maximum length of 353 nucleotides."

Applicants submit that while the claim term "[a] polynucleotide comprising a contiguous sequence that is identical to a sequence of at least 12 contiguous nucleotides ... wherein said polynucleotide has a maximum length of 353 nucleotides" may not be explicitly recited in the Specification one of skill in the art would have understood that Applicants were in possession of the claimed invention from reviewing the Specification.¹

Explicit support for the upper limit of "wherein said polynucleotide has a maximum length of 353 nucleotides" is found in the Specification. The complete nucleotide sequence of a 353 nucleotides long clone 81 of HCV cDNA is shown in Figure 4 and described in the Specification in section IV.C.1. Its use as a probe for identifying RNA from liver by Northern hybridization is disclosed in the Specification at page 170, line 28 – page 171, line 19.

Explicit support for the lower limit of "[a] polynucleotide comprising a contiguous sequence that is identical to a sequence of at least 12 contiguous nucleotides" is found in the Specification. Applicants note that the Examiner has identified support for term specifying a minimum length of polynucleotide: "[a] polynucleotide comprising a contiguous sequence that is identical to a sequence of at least 12 contiguous nucleotides" on page 26, line 21 and page 61, line 16 of the Specification. The Examiner has also noted disclosure related to polynucleotide probes of 12-30 nucleotides in length at page 69 and sections IV.A.5-25, 27-28, 30, etc. of the Specification. Therefore, there is explicit support for both the upper and lower limit of the claimed range of 12-353 nucleotides.

A representative number of species encompassing the range of 12-353 nucleotides is also disclosed in the Specification. Section IV.A.3 (page 93, lines 28-30) discloses a 80 nucleotide long probe derived from the sequence of Figure 1. Figure 1 discloses a 155 nucleotide long sequence according to claim 60. A 108 nucleotide long polynucleotide probe generated from the 353 nucleotide long clone 81 sequence using two 16 nucleotide long PCR primers is disclosed on pages 175-176 of the Specification. A 161 nucleotide long RNA ("polynucleotide") isolated by use of the 108 nucleotide probe derived from clone 81 (Figure 4) is disclosed at page 176, line 34.

¹ Applicants note that the claims are not limited to "probes" but to all polynucleotides encompassing at least 12 nucleotides of the specified sequence.

Given the complete nucleotide sequence of a 353 bp long polynucleotide and the specific disclosure of polynucleotides encompassing 12, 15, 16, 20, 30, 80, 108, and 161 long species within the 353 long sequence, Applicants submit that one of skill in the art would understand that Applicants had possession of the genus of polynucleotides specified as: "[a] polynucleotide comprising a contiguous sequence that is identical to a sequence of at least 12 contiguous nucleotides shown in either strand of the nucleotide sequence in ... wherein said polynucleotide has a maximum length of 353 nucleotides."

(ii) Claim term: at least 12 contiguous nucleotides ... wherein said polynucleotide has a maximum length of 108 nucleotides

Claims 83, 86 and 87 specify: "[at least 12 contiguous nucleotides]... wherein said polynucleotide has a maximum length of 108 nucleotides."

As discussed above, explicit support for the lower limit of "[a] polynucleotide comprising a contiguous sequence that is identical to a sequence of at least 12 contiguous nucleotides" is found in the Specification. "A polynucleotide comprising a contiguous sequence that is identical to a sequence of at least 12 contiguous nucleotides" is disclosed on page 26, line 21 and page 61, line 16 of the Specification. The Examiner has also noted disclosure related to polynucleotide probes of 12-30 nucleotides in length at page 69 and sections IV.A.5-25, 27-28, 30, etc. of the Specification. Section IV.A.3 (page 93, lines 28-30) discloses a 80 nucleotide long probe derived from the sequence of Figure 1. Figure 1 discloses a 155 nucleotide long sequence according to claim 60. The upper limit of a 108 nucleotide long polynucleotide probe generated from the 353 nucleotide long clone 81 sequence using two 16 nucleotide long PCR primers is disclosed on pages 175-176 of the Specification.

Therefore, there is explicit support for both the upper and lower limit of the claimed range of 12-108 nucleotides and a representative number of species encompassing the range of 12-108 nucleotides.

(iii) Claim term: at least 12 contiguous nucleotides ... wherein said polynucleotide has a maximum length of 161 nucleotides

Claims 78, 81 and 82 specify: "[at least 12 contiguous nucleotides]... wherein said polynucleotide has a maximum length of 161 nucleotides."

As discussed above, explicit support for the lower limit of "[a] polynucleotide comprising a contiguous sequence that is identical to a sequence of at least 12 contiguous nucleotides" is found in the Specification. "A polynucleotide comprising a contiguous sequence that is identical to a sequence of at least 12 contiguous nucleotides" is disclosed on page 26, line 21 and page 61, line 16 of the Specification. The Examiner has also noted disclosure related to polynucleotide probes of 12-30 nucleotides in length at page 69 and sections IV.A.5-25, 27-28, 30, etc. of the Specification. Section IV.A.3 (page 93, lines 28-30) discloses a 80 nucleotide long probe derived from the sequence of Figure 1. Figure 1 discloses a 155 nucleotide long sequence according to claim 60. A 108 nucleotide long polynucleotide probe generated from the 353 nucleotide long clone 81 sequence using two 16 nucleotide long PCR primers is disclosed on pages 175-176 of the Specification. The upper limit of a 161 nucleotide long RNA ("polynucleotide") isolated by use of the 108 nucleotide probe derived from clone 81 (Figure 4) is disclosed at page 176, line 34.

Therefore, there is explicit support for both the upper and lower limit of the claimed range of 12-161 nucleotides and a representative number of species encompassing the range of 12-161 nucleotides.

(iv) Claim term: at least 12 contiguous nucleotides ... wherein said polynucleotide has a maximum length of 586 nucleotides

Claims 61, 63, 65, 67, 69, 71 and 73 specify "[a] polynucleotide comprising a contiguous sequence that is identical to a sequence of at least 12 contiguous nucleotides, ... wherein said polynucleotide has a maximum length of 586 nucleotides."

As discussed above, explicit support for the lower limit of "[a] polynucleotide comprising a contiguous sequence that is identical to a sequence of at least 12 contiguous nucleotides" is found in the Specification. "A polynucleotide comprising a contiguous sequence that is identical to a sequence of at least 12 contiguous nucleotides" is disclosed on page 26, line 21 and page 61, line 16 of the Specification. The Examiner has also noted disclosure related to polynucleotide probes of 12-30 nucleotides in length at page 69 and sections IV.A.5-25, 27-28, 30, etc. of the Specification.

Explicit support for the upper limit of "wherein said polynucleotide has a maximum length of 586 nucleotides" is found in the Specification. HCV polynucleotides 586 nucleotides in

length are disclosed in section IV.C.3 and specifically at page 176, lines 34-35 of the Specification. The preparation of the 586 nucleotides long polynucleotide is disclosed at page 175, line 7 – page 176, line 35.

The complete nucleotide sequence of the 586 nucleotide long polynucleotide can be obtained from aligning the clone 36 and clone 37b primers on page 175, lines 20 and 24 of the Specification with the sequence disclosed in Figures 5, 8 and 10 of overlapping clones 35, 36 and 37b.

A representative number of species encompassing the range of 12-586 nucleotides is also disclosed in the Specification. Section IV.A.3 (page 93, lines 28-30) discloses a 80 nucleotide long probe derived from the sequence of Figure 1. Figure 1 also discloses a 155 nucleotide long sequence according to claim 60. A 108 nucleotide long polynucleotide probe generated from the 353 nucleotide long clone 81 sequence using two 16 nucleotide long PCR primers is disclosed on pages 175-176 of the Specification. A 161 nucleotide long RNA ("polynucleotide") isolated by use of the 108 nucleotide probe derived from clone 81 (Figure 4) is disclosed at page 176, line 34.

Nucleotide sequences of polynucleotides comprising a contiguous sequence that is identical to a sequence of at least 12 contiguous nucleotides ... wherein said polynucleotide has a maximum length of 586 nucleotides, are also disclosed in relation to the 586 base polynucleotide at page 176, lines 18-24 and 34-35 of the Specification, in Figure 5 (a polynucleotide 406 nucleotides in length), Figure 8 (a polynucleotide 480 nucleotides in length), and Figure 10 (a polynucleotide 268 nucleotides in length).

Therefore, Applicants submit that one of skill in the art would understand that Applicants had possession of the genus of polynucleotides specified as: [a] polynucleotide comprising a contiguous sequence that is identical to a sequence of at least 12 contiguous nucleotides shown in either strand of the nucleotide sequence in Figures 1, 3, 4, 14, 26, 57, 59, 62, 72, or the nucleotide sequence in any of the viral cDNA inserts in a lambda gt-11 cDNA library deposited as ATCC No. 40394, wherein said polynucleotide has a maximum length of 586 nucleotides.

Thus, the Specification provides an adequate description of a genus of HCV DNA sequences of at least 12 and up to 108, 161, 353 and 586 nucleotides in length by identifying

DNA sequences at the lower and upper limits and a representative number of DNA sequences falling within the scope of the genus and constituting a substantial portion of the genus.

Claims 76-77, 88, 91-93, 96-98, 101-103, 106-108, 111-113, 116-118, 121-123, 126-128, 131-133, 136-138, 141-143, 145-148, 151-153, 156-158, 161-163, 166-168, 171-173, 176-178, 181-183, 186-188, 191-193, 196-198, 201-203, 206-208, 211-213, 216-218, 221-223, 226-228, 231-233, 236-238, 240-243, 246-248, 250-252, 255-257, 260-262, 265-268, 271-273, 276-278, 281-284, 287-289, 292-294, 297-299, 302-304, 307-309, 312-314, 317-319, 322-324, 327-329, and 332-340 depend from claims 60-73, 78, 81-83, 86 and 87 whose written description support in the specification under 35 U.S.C. § 112, first paragraph is discussed above.

Therefore Applicants respectfully request withdrawal of the rejections under 35 U.S.C. §112, first paragraph.

CONCLUSION

In light of the arguments set forth above, Applicants earnestly believe that they are entitled to a letters patent, and respectfully solicit the Examiner to expedite prosecution of this patent application to issuance. If it is determined that a telephone conference would expedite the prosecution of this application, the Examiner is invited to telephone the undersigned at the number given below.

In the event the U.S. Patent and Trademark office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 03-1952 referencing docket no. 223002006316. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

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Respectfully submitted,

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